



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2019-0565; FRL-10003-30]

### Notice of Intent to Suspend Certain Pesticide Registrations

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice, pursuant the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), publishes a Notice of Intent to Suspend certain pesticide registrations issued by EPA. The Notice of Intent to Suspend was issued following the Agency's issuance of a Data Call-In Notice (DCI), which required the registrant of the affected pesticide products containing a certain pesticide active ingredient to take appropriate steps to secure certain data, and following the registrant's failure to submit these data or to take other appropriate steps to secure the required data. The subject data were determined to be required to maintain in effect the existing registrations of the affected products. Failure to comply with the data requirements of a DCI is a basis for suspension of the affected registrations under FIFRA.

**DATES:** The Notice of Intent to Suspend included in this *FEDERAL REGISTER* notice will become a final and effective suspension order automatically by operation of law 30 days after the date of the registrant's receipt of the mailed Notice of Intent to Suspend or, if the mailed Notice of Intent to Suspend is returned to the EPA Administrator as undeliverable, if delivery is refused, or if the EPA Administrator otherwise is unable to accomplish delivery to the registrant after making reasonable efforts to do so, the Notice of Intent to Suspend becomes effective 30 days after the date of publication of this notice in the *FEDERAL REGISTER*, unless, during that time, a timely and adequate request for a hearing is made by a person adversely affected by the Notice

of Intent to Suspend, or the registrant has satisfied the EPA Administrator that the registrant has complied fully with the requirements that served as a basis for the Notice of Intent to Suspend.

Unit IV. explains what must be done to avoid suspension under this notice (i.e., how to request a hearing or how to comply fully with the requirements that served as a basis for the Notice of Intent to Suspend).

**FOR FURTHER INFORMATION CONTACT:** Erin Dandridge, Antimicrobial Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001, telephone number: (703) 347-0185, email: *dandridge.erin@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, farm worker and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

*B. How Can I Get Copies of this Document and Other Related Information?*

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2019-0565, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), William Jefferson Clinton West Building., Room. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from

8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

## **II. Registrant Issued Notice of Intent to Suspend Active Ingredient, Product(s) Affected, and Date(s) Issued**

The registrant and products subject to this Notice of Intent to Suspend are listed in Table 1. A Notice of Intent to Suspend was sent to the registrant of the affected products via the U.S. Postal Service, first class mail, return receipt requested.

**Table 1. --List of Registrant and Products Subject to Suspension**

<b>Registrant Affected</b>	<b>Active Ingredient</b>	<b>EPA Registration Number</b>	<b>Product Name</b>	<b>Date EPA Issued Notice of Intent to Suspend</b>
Qualco, Inc.	Dialkyl*methyl benzyl ammonium chloride *(60%C14, 30% C16, 5% C18, 5% C12)	3525-22	Utikem Algaesan Multi-Purpose Algacide	July 27, 2020
Qualco, Inc.	Dialkyl*methyl benzyl ammonium chloride *(60%C14, 30% C16, 5% C18, 5% C12)	3525-78	Algae Destroyer	July 27, 2020
Qualco, Inc.	Alkyl*dimethyl benzyl ammonium chloride* (60%C14, 30%C16, 5%C18, 5%C12)	3525-94	Coastal Pool Aid Powder Surface Sanitizer	July 27, 2020
Qualco, Inc.	Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 25%C12, 15%C16)	3525-97	Winter Aid	July 27, 2020
Qualco, Inc.	Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 25%C12, 15%C16)	3525-99	Coastal Pool Deodor	July 27, 2020
Qualco, Inc.	Alkyl* dimethyl benzyl ammonium chloride	3525-100	Winter Tablets "G"	July 27, 2020

	*(60%C14, 25%C12, 15%C16)			
Qualco, Inc.	Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 25%C12, 15%C16)	3525-103	Cal Jet Algaecide Liquid	July 27, 2020
Qualco, Inc.	Alkyl* dimethyl benzyl ammonium chloride *(95%C14, 3%C12, 2%C16)	3525-104	Iso Clor "C" Super Stabilized Chlorinating Powder	July 27, 2020
Qualco, Inc.	Dialkyl*methyl benzyl ammonium chloride *(60%C14, 30% C16, 5% C18, 5% C12)	3525-106	Liquid Algaecide	July 27, 2020
Qualco, Inc.	Dialkyl*methyl benzyl ammonium chloride *(60%C14, 30% C16, 5% C18, 5% C12)	3525-118	Coastal Concentrate 50	July 27, 2020

### III. Basis for Issuance of Notice of Intent to Suspend; Requirement List

The registrant failed to submit the data or information required by the Data Call-In Notice, or to take other appropriate steps to secure the required data for their pesticide products listed in Table 2 of this unit.

While the Agency did not receive a certified mail return receipt from Ms. Schaub, the agent for Qualco, Inc., or from Qualco, Inc. for the Product Specific Data Call-In (PDCI) Notice requiring data generation and submission for EPA Reg. Nos. 3525-22, 3525-78, 3525-94, 3524-97, 3525-99, 3525-100, 3525-103, 3525-104, 3525-106, and 3525-118, the agency has correspondence from the company's representative after the PDCI Notices were issued evidencing that Ms. Schaub and thus Qualco, Inc. received the PDCIs and were aware of the data requirements.

**Table 2-A. --List of Requirements for EPA Registration Number 3525-94**

Guideline Number as Listed in	Requirement Name	Date EPA Issued DCI	Date Registrant Received DCI	Final Data Due Date	Reason for Notice of Intent to
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<b>Applicable DCI</b>					<b>Suspend *</b>
830.1550	Product Identity and Composition	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.1600	Description of Materials Used to Produce the Product	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.1620	Description of Production Process	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.1650	Description of Formulation Process	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.1670	Discussion of Formation of Impurities	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.1700	Preliminary Analysis	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.1750	Certified Limits	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.1800	Enforcement Analytical Method	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.6302	Color	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.6303	Physical State	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.6304	Odor	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.6314	Oxidizing or Reducing Action	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.6315	Flammability	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4

830.6316	Explosibility	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.6317	Storage Stability	3/11/2015	Confirmation through Correspondence	07/09/2016	2 & 4
830.6319	Miscibility	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.6320	Corrosion Characteristics	3/11/2015	Confirmation through Correspondence	07/09/2016	2 & 4
830.6321	Dielectric Breakdown Voltage	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.7000	pH	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.7050	UV/Visible Absorption	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.7100	Viscosity	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.7200	Melting Point/Melting Range	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.7220	Boiling Point/Boiling Range	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.7300	Density/Relative Density	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.7370	Dissociation Constants in Water	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.7560	Partition Coefficient (n-octanol/water, Generator Column Method	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4

830.7570	Partition Coefficient (n-octanol/water, Estimation by Liquid Chromatography	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.7840	Water Solubility: Column Elution Method, Shake Flask Method	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.7860	Water Solubility, Generator Column Method	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
830.7950	Vapor Pressure	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
870.1100	Acute Oral Toxicity	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
870.1200	Acute Dermal Toxicity	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
870.1300	Acute Inhalation Toxicity	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
870.2500	Acute Dermal Irritation	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
870.2600	Skin Sensitization	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
870.2400	Acute Eye Irritation	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
810.2100	Sterilants	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
810.2200	Disinfectants for Use on Hard Surfaces	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
810.2300	Sanitizers for Use on Hard Surfaces	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
810.2400	Disinfectants and Sanitizers for Use on Fabrics and	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4

	Textiles				
810.2500	Air Sanitizers	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4
810.2600	Disinfectants for Use in Water	3/11/2015	Confirmation through Correspondence	11/09/2015	2 & 4

\* Table Notes:

<sup>1</sup> No 90-day response received.

<sup>2</sup> Inadequate 90-day response received.

<sup>3</sup> No data received.

<sup>4</sup> Inadequate data received.

**Table 2-B. --List of Requirements for EPA Registration Numbers: 3525-22; 3525-78; 3525-97; 3525-99; 3525-100; 3525-103; 3525-106; and 3525-118**

<b>Guideline Number as Listed in Applicable DCI</b>	<b>Requirement Name</b>	<b>Date EPA Issued DCI</b>	<b>Date Registrant Received DCI</b>	<b>Final Data Due Date</b>	<b>Reason for Notice of Intent to Suspend *</b>
830.1550	Product Identity and Composition	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.1600	Description of Materials Used to Produce the Product	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.1620	Description of Production Process	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.1650	Description of Formulation Process	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.1670	Discussion of Formation of Impurities	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.1700	Preliminary Analysis	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.1750	Certified Limits	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.1800	Enforcement Analytical Method	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4



830.6302	Color	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.6303	Physical State	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.6304	Odor	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.6314	Oxidizing or Reducing Action	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.6315	Flammability	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.6316	Explosibility	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.6317	Storage Stability	3/06/2015	Confirmation through Correspondence	07/04/2016	2 & 4
830.6319	Miscibility	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.6320	Corrosion Characteristics	3/06/2015	Confirmation through Correspondence	07/04/2016	2 & 4
830.6321	Dielectric Breakdown Voltage	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.7000	pH	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.7050	UV/Visible Absorption	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.7100	Viscosity	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.7200	Melting Point/Melting Range	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4

830.7220	Boiling Point/Boiling Range	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.7300	Density/Relative Density	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.7370	Dissociation Constants in Water	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.7560	Partition Coefficient (n-octanol/water, Generator Column Method	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.7570	Partition Coefficient (n-octanol/water, Estimation by Liquid Chromatography	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.7840	Water Solubility: Column Elution Method, Shake Flask Method	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830.7860	Water Solubility, Generator Column Method	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
830. 7950	Vapor Pressure	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
870.1100	Acute Oral Toxicity	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
870.1200	Acute Dermal Toxicity	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
870.1300	Acute Inhalation Toxicity	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
870.2500	Acute Dermal Irritation	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
870.2600	Skin Sensitization	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4

870.2400	Acute Eye Irritation	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
810.2100	Sterilants	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
810.2200	Disinfectants for Use on Hard Surfaces	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
810.2300	Sanitizers for Use on Hard Surfaces	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
810.2400	Disinfectants and Sanitizers for Use on Fabrics and Textiles	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
810.2500	Air Sanitizers	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4
810.2600	Disinfectants for Use in Water	3/06/2015	Confirmation through Correspondence	11/04/2015	2 & 4

\* Table Notes:

<sup>1</sup> No 90-day response received.

<sup>2</sup> Inadequate 90-day response received.

<sup>3</sup> No data received.

<sup>4</sup> Inadequate data received.

**Table 2-C. --List of Requirements for EPA Registration Number 3525-104**

<b>Guideline Number as Listed in Applicable DCI</b>	<b>Requirement Name</b>	<b>Date EPA Issued DCI</b>	<b>Date Registrant Received DCI</b>	<b>Final Data Due Date</b>	<b>Reason for Notice of Intent to Suspend*</b>
830.1550	Product Identity and Composition	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.1600	Description of Materials Used to Produce the Product	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.1620	Description of Production Process	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.1650	Description of Formulation Process	3/04/2015	Confirmation through	11/02/2015	1 & 3

			Correspondence		
830.1670	Discussion of Formation of Impurities	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.1700	Preliminary Analysis	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.1750	Certified Limits	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.1800	Enforcement Analytical Method	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.6302	Color	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.6303	Physical State	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.6304	Odor	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.6314	Oxidizing or Reducing Action	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.6315	Flammability	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.6316	Explosibility	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.6317	Storage Stability	3/04/2015	Confirmation through Correspondence	07/02/2016	1 & 3
830.6319	Miscibility	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.6320	Corrosion Characteristics	3/04/2015	Confirmation through Correspondence	07/02/2016	1 & 3
830.6321	Dielectric Breakdown Voltage	3/04/2015	Confirmation through	11/02/2015	1 & 3

			Correspondence		
830.7000	pH	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.7050	UV/Visible Absorption	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.7100	Viscosity	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.7200	Melting Point/Melting Range	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.7220	Boiling Point/Boiling Range	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.7300	Density/Relative Density	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.7370	Dissociation Constants in Water	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.7560	Partition Coefficient (n-octanol/water, Generator Column Method	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.7570	Partition Coefficient (n-octanol/water, Estimation by Liquid Chromatography	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.7840	Water Solubility: Column Elution Method, Shake Flask Method	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830.7860	Water Solubility, Generator Column Method	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
830. 7950	Vapor Pressure	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
870.1100	Acute Oral Toxicity	3/04/2015	Confirmation through	11/02/2015	1 & 3

			Correspondence		
870.1200	Acute Dermal Toxicity	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
870.1300	Acute Inhalation Toxicity	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
870.2500	Acute Dermal Irritation	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
870.2600	Skin Sensitization	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
870.2400	Acute Eye Irritation	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
810.2100	Sterilants	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
810.2200	Disinfectants for Use on Hard Surfaces	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
810.2300	Sanitizers for Use on Hard Surfaces	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
810.2400	Disinfectants and Sanitizers for Use on Fabrics and Textiles	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
810.2500	Air Sanitizers	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3
810.2600	Disinfectants for Use in Water	3/04/2015	Confirmation through Correspondence	11/02/2015	1 & 3

\* Table Notes:

<sup>1</sup> No 90-day response received.

<sup>2</sup> Inadequate 90-day response received.

<sup>3</sup> No data received.

<sup>4</sup> Inadequate data received.

#### **IV. Attachment III Suspension Report - Explanatory Appendix**

1. The letter sent to the registrant contains an Attachment III - Explanatory Appendix.

This Explanatory Appendix also follows below and provides provides a discussion of the basis

for the Notice of Intent to Suspend issued herewith.

*A. Aklyl Dimethyl Benzyl Ammonium Chloride (ADBAC)*

On March 4, 2015, March 6, 2015, and March 11, 2015, the Agency issued the Reregistration Eligibility Decision Document (RED) PDCI Notices numbered: 069184-30960, 069137-30946, 069119-30941, and 069104-30932 pursuant to FIFRA section 4(g)(2)(B), which required the registrants of products containing ADBAC used as an active ingredient to develop and submit certain data. The data/information were determined to be necessary to satisfy the reregistration requirements of FIFRA section 4(g). Failure to comply with the requirements of the RED PDCI is a basis for suspension under FIFRA section 3(c)(2)(B).

The Agency sent PDCIs: 069184-30960, 069137-30946, 069119-30941, and 069104-30932 on March 4, 6, and 11, 2015 to Qualco, Inc. via the email address provided to the Agency for Ms. Debbie Schaub, who was the designated company representative. A Microsoft Outlook server response email for PDCI-069104-30932 was received on March 11, 2015 by the Agency to indicate delivery to Ms. Schaub was complete. Subsequently, the PDCIs were re-sent on March 27, 2015 to an alternative Qualco, Inc. email address for Ms. Schaub because no response was received after email delivery to the original email address.

Following a DCI issuance, registrants are required to submit a 90-day response electing how they will satisfy the DCI data requirements. Qualco, Inc. failed to submit a 90-day response electing how it would satisfy the DCI data requirements.

After three years of no response from Qualco, Inc. on May 21, 2018, the Agency sent emails to Qualco, Inc. to the attention of Ms. Schaub and Mr. Peter Ferentinos, who is another designated Qualco, Inc. representative. In the emails, the Agency discussed the severity of the PDCI response failures by Qualco, Inc. These emails also forwarded once again the originally

sent PDCIs and email with attachments and instructions. The Agency received Microsoft Outlook server response emails for each PDCI (069184-30960, 069137-30946, 069119-30941, and 069104-30932) email that confirmed that delivery to both addresses had been completed on May 21, 2018.

After hearing nothing from Qualco between May 21 and October 31, 2018 the Agency emailed a Notification of Deficiency letter to Qualco, Inc. on October 31, 2018 to the attention of Ms. Schaub that warned the registrant of the pending suspension of the affected Qualco, Inc. ADBAC products. The email listed the overdue PDCIs and the attached letter noted the specific deficient data requirements for each listed PDCI, discussed the lack of an adequate 90-day response for each PDCI, described how to respond to the deficiency letter, included the list of then affected (EPA Reg. Nos.: 3525-22, 3525-78, 3525-90, 3525-92, 3525-94, 3525-97, 3525-99, 3525-100, 3525-103, 3525-104, 3525-106, and 3525-118), and stated that appropriate and adequate data to satisfy the overdue data requirements must be received by the Agency within 10 business days measured from the letter receipt by Qualco, Inc. in order to avoid issuance of Notices of Intent to Suspend. The Agency received a Microsoft Outlook server email on October 31, 2018 indicating that the email and the attached information had been received by Qualco, Inc. on October 31, 2018.

The same October 31, 2018 Notification of Deficiency letter was mailed via the US Postal Service on November 8, 2018 along with another Notification of Deficiency letter for another chemical case (Busan 77).

The Agency subsequently sent Qualco, Inc. an email to the attention of Ms. Schaub on November 20, 2018 stating that a voicemail had been left for Ms. Schaub. The November 20, 2018 email and voicemail both requested a meeting to discuss the ADBAC and Busan 77 DCIs.



The Agency proposed meeting dates and times in the November 20, 2018 email. The November 20, 2018 email included the October 31, 2018 email discussed above as part of its chain of prior correspondence.

Ms. Schaub responded by email to the Agency's November 20, 2018 email on November 26, 2018. The Agency's October 31, 2018 email with the initial Notification of Deficiency warning letter was included in the chain of emails that were part of her email response. Qualco, Inc., through Ms. Schaub, suggested scheduling a November 28, 2018 meeting in her November 26, 2018 email.

An Agency email response was sent to Ms. Schaub on November 26, 2018 confirming the scheduling of a November 28, 2018 teleconference meeting at 1pm. On November 28, 2018 the Agency and Ms. Schaub met via teleconference to discuss the overdue data requirements of PDCIs: 069104-30932, 069119-30941, 069137-30946, 069184-30960, and the affected Qualco products (EPA Reg. Nos.: 3525-22, 3525-78, 3525-90, 3525-92, 3525-94, 3525-97, 3525-99, 3525-100, 3525-103, 3525-104, 3525-106, and 3525-118).

Ms. Schaub subsequently sent the Agency an email on December 3, 2018 to inform the Chemical Review Manager that a DCI response was being put together for ADBAC, that errors were received after an attempt to upload files to the EPA CDX, and to ask what other specific forms were required for the PDCI response.

The Agency responded by email on December 3, 2018 and attached another copy of the PDCI-069104-30932 for Ms. Schaub's reference. This PDCI was attached as a representative DCI to illustrate what needed to be done by Qualco to adequately respond to all issued PDCIs. The Agency once again stated that instructions and required forms for Qualco's response are explained in the PDCI. The CDX helpdesk contact information was provided for Ms. Schaub's

reference. However, the Agency requested that Qualco's responses be sent directly by email to the Chemical Review Manager to avoid CDX errors or the product suspension process would continue. In the Agency December 3, 2018 email, a list of all the affected Qualco products pending suspension (EPA Reg. Nos.: 3525-22, 3525-78, 3525-94, 3525-97, 3525-99, 3525-100, 3525-103, 3525-104, 3525-106, and 3525-118) was attached. The December 3, 2018 email also noted that two products (3525-90 and 3525-92) originally listed in the October 31, 2018 letter had been voluntarily cancelled.

Ms. Schaub responded to the Agency's December 3, 2018 email chain by providing attachments, including data matrices, Confidential Statement of Formulas (CSF), and other forms, for 5 of the 10 products pending suspension (EPA Reg. Nos.: 3525-22, 3525-78, 3525-94, 3525-106, and 3525-118). Ms. Schaub stated in the December 3, 2018 email that additional forms and responses for the other 5 products (EPA Reg. Nos.: 3525-103, 3525-104, 3525-97, 3525-99, and 3525-100) would be submitted through a second CDX attempt.

On December 4, 2018 the Agency stated through email that the submitted ADBAC PDCI responses would be reviewed. The Agency requested that Ms. Schaub submit the remaining responses and suggested that, if some products are dormant, then Qualco may opt to voluntarily cancel those products.

On December 5, 2018, an email from the CDX system to the EPA Antimicrobials Division Reevaluation mailbox was received. The December 5, 2018 CDX email indicated that a DCI response for only PDCI-069137-30946 had been submitted and included data matrices, citation forms, and correspondence for only EPA Registration Nos.: 3525-100, 3525-103, 3525-97, and 3525-99. No submissions were provided for EPA registration number 3525-104 by email or CDX.

The Agency sent an email on December 5, 2018 to Ms. Schaub informing Qualco that the emailed submissions were reviewed but numerous errors were found. The Agency's December 5, 2018 email requested that corrected responses be sent as soon as possible. The following list summarizes the errors.

- The "Requirements Status & Registrant's Response" forms listed response code 9; however, this code does not exist for PDCI responses and is not an adequate or appropriate response. This error pertains to the following products: EPA Reg. Nos.: 3525-22, 3525-78, 3525-94, 3525-106, and 3525-118.

- The "Requirements Status & Registrant's Response" forms were not adequately completed. This error pertains to the following products: EPA Reg. Nos.: 3525-97, 3525-99, 3525-100, and 3525-103.

- The data matrices submitted for EPA Reg. Nos.: 3525-22, 3525-78, 3525-94, 3525-97, 3525-99, 3525-100, 3525-103, and 3525-106 are missing anything to address the 810 data requirements.

- The Formulator's Exemption form for EPA Reg. No.: 3525-118 states that the product's source is EPA Reg. No. 3525-118, which is stating that the product is formulated with itself and this is neither an adequate nor appropriate response.

- Qualco, Inc. chose the option to cite another registrant's study for product specific data for the following products: EPA Reg. Nos.: 3525-22, 3525-78, 3525-97, 3525-99, 3525-100, 3525-103, and 3525-106. However, Qualco did not provide the appropriate MRID Accession number(s) or an adequately completed "Certification with Respect to Data Compensation Requirements" form. The submitted "Certification with Respect to Citation of Data" forms cannot state "cite all" for PDCIs unless the "Certification with Respect to Data Compensation"

form is submitted with the appropriate MRID Accession number(s).

Qualco, Inc. has not responded to the Agency's December 5, 2018 email and has not to-date satisfied the overdue PDCI requirements for its affected products. Therefore, this Notice of Intent to Suspend is being issued for EPA Registration Nos.: 3525-22, 3525-78, 3525-94, 3525-97, 3525-99, 3525-100, 3525-103, 3525-104, 3525-106, and 3525-118.

#### **V. How to Avoid Suspension under this Notice?**

1. You may avoid suspension under this notice if you or another person adversely affected by this notice properly request a hearing within 30 days of your receipt of the Notice of Intent to Suspend by mail or, if you did not receive the notice that was sent to you via USPS first class mail return receipt requested, then within 30 days from the date of publication of this *FEDERAL REGISTER* notice (see **DATES**). If you request a hearing, it will be conducted in accordance with the requirements of FIFRA section 6(d) (7 U.S.C. 136d) and the Agency's procedural regulations in 40 CFR part 164. Section 3(c)(2)(B) of FIFRA (7 U.S.C. 136a), however, provides that the only allowable issues which may be addressed at the hearing are whether you have failed to take the actions which are the bases of this notice and whether the Agency's decision regarding the disposition of existing stocks is consistent with FIFRA. Therefore, no substantive allegation or legal argument concerning other issues, including but not limited to the Agency's original decision to require the submission of data or other information, the need for or utility of any of the required data or other information or deadlines imposed, any allegations of errors or unfairness in any proceedings before an arbitrator, and the risks and benefits associated with continued registration of the affected product, may be considered in the proceeding. The Administrative Law Judge shall by order dismiss any objections which have no bearing on the allowable issues which may be considered in the proceeding. Section

3(c)(2)(B)(iv) of FIFRA provides that any hearing must be held and a determination issued within 75 days after receipt of a hearing request. This 75-day period may not be extended unless all parties in the proceeding stipulate to such an extension. If a hearing is properly requested, the Agency will issue a final order at the conclusion of the hearing governing the suspension of your products. A request for a hearing pursuant to this notice must:

- Include specific objections which pertain to the allowable issues which may be heard at the hearing.
- Identify the registrations for which a hearing is requested.
- Set forth all necessary supporting facts pertaining to any of the objections which you have identified in your request for a hearing.

If a hearing is requested by any person other than the registrant, that person must also state specifically why he/she asserts that he/she would be adversely affected by the suspension action described in this notice. Three copies of the request must be submitted to: Hearing Clerk, 1900, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

An additional copy should be sent to the person who signed this notice. The request must be received by the Hearing Clerk by the applicable 30<sup>th</sup> day deadline as measured from your receipt of the Notice of Intent to Suspend by mail or publication of this notice, as set forth in **DATES** and in Unit IV.1., in order to be legally effective. The 30-day time limit is established by FIFRA and cannot be extended for any reason. Failure to meet the 30-day time limit will result in automatic suspension of your registrations by operation of law and, under such circumstances, the suspension of the registration for your affected products will be final and effective at the close of business on the applicable 30<sup>th</sup> day deadline as measured from your

receipt of the Notice of Intent to Suspend by mail or publication of this notice, as set forth in **DATES** and in Unit IV.1., and will not be subject to further administrative review. The Agency's rules of practice at 40 CFR 164.7 forbid anyone who may take part in deciding this case, at any stage of the proceeding, from discussing the merits of the proceeding *ex parte* with any party or with any person who has been connected with the preparation or presentation of the proceeding as an advocate or in any investigative or expert capacity, or with any of their representatives. Accordingly, the following EPA offices, and the staffs thereof, are designated as judicial staff to perform the judicial function of EPA in any administrative hearings on this Notice of Intent to Suspend: The Office of the Administrative Law Judges, the Office of the Environmental Appeals Board, the EPA Administrator, the EPA Deputy Administrator, and the members of the staff in the immediate offices of the EPA Administrator and EPA Deputy Administrator. None of the persons designated as the judicial staff shall have any *ex parte* communication with trial staff or any other interested person not employed by EPA on the merits of any of the issues involved in this proceeding, without fully complying with the applicable regulations.

2. You may also avoid suspension if, within the applicable 30-day deadline period as measured from your receipt of the Notice of Intent to Suspend by mail or publication of this notice, as set forth in **DATES** and in Unit IV.1., the Agency determines that you have taken appropriate steps to comply with the FIFRA section 3(c)(2)(B) DCI notice. In order to avoid suspension under this option, you must satisfactorily comply with Table 2.--List of Requirements in Unit II., for each product by submitting all required supporting data/information described in Table 2 of Unit. II. and in the Explanatory Appendix (in the docket for this *FEDERAL REGISTER* notice) to the following address (preferably by certified mail):

Office of Pesticide Programs, Antimicrobials Division (7510P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

For you to avoid automatic suspension under this notice, the Agency must also determine within the applicable 30-day deadline period that you have satisfied the requirements that are the bases of this notice and so notify you in writing. You should submit the necessary data/information as quickly as possible for there to be any chance the Agency will be able to make the necessary determination in time to avoid suspension of your products. The suspension of the registrations of your company's products pursuant to this notice will be rescinded when the Agency determines you have complied fully with the requirements which were the bases of this notice. Such compliance may only be achieved by submission of the data/information described in Table 2 of Unit II.

#### **VI. Status of Products that Become Suspended**

Your product will remain suspended, however, until the Agency determines you are in compliance with the requirements which are the bases of this notice and so informs you in writing.

After the suspension becomes final and effective, the registrants subject to this notice, including all supplemental registrants of products listed in Table 1 of Unit II., may not legally distribute, sell, use, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, the products listed in Table 1 of Unit II. Persons other than the registrants subject to this notice, as defined in the preceding sentence, may continue to distribute, sell, use, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, the products listed in Table 1 of Unit II. Nothing in this notice authorizes any person to distribute, sell, use, offer for sale, hold

for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person, the products listed in Table 1 of Unit II. in any manner which would have been unlawful prior to the suspension.

If the registrations for your products, listed in Table 1 of Unit II., are currently suspended as a result of failure to comply with another FIFRA section 3(c)(2)(B) DCI notice or FIFRA Section 4 Data Requirements notice, this notice, when it becomes a final and effective order of suspension, will be in addition to any existing suspension, i.e., all requirements which are the bases of the suspension must be satisfied before the registration will be reinstated.

It is the responsibility of the basic registrant to notify all supplementary registered distributors of a basic registered product that this suspension action also applies to their supplementary registered products. The basic registrant may be held liable for violations committed by their distributors.

Any questions about the requirements and procedures set forth in this notice or in the subject FIFRA section 3(c)(2)(B) DCI notice, should be addressed to the person listed under **FOR FURTHER INFORMATION CONTACT.**

(Authority: 7 U.S.C. 136 *et seq.*)

Dated: August 19, 2020.

**Anita Pease,**

*Director,*

*Antimicrobials Division, Office of Pesticide Programs.*

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